PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No:	09/765,151
Filing Date:	January 17, 2001
Applicant:	Gilbert R. Gonzales, et al.
Title:	COMBINATION AND METHOD INCLUDING A VISUAL MARKER FOR DETERMINING COMPLIANCE WITH A MEDICATION REGIMEN
Art Unit:	3732
Examiner:	Anu Ramana
Attorney Docket:	PEDI-27

Cincinnati, Ohio 45202 March 18, 2005

Commissioner for Patents
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DECLARATION OF GILBERT R. GONZALES UNDER 37 C.F.R § 1.132

I, Gilbert R. Gonzales, hereby state and declare the following:

I am a named inventor on the present application, U.S. Patent Application Serial No. 09/765,151 ("the '151 Application"), which is assigned to PediaMed Pharmaceuticals, Inc. of Florence, Kentucky. I have B.Sc. (1973) and M.D. (1977) degrees from the University of Arizona. I have treated patients for various afflictions, and have held the following positions: Lt., U.S. Public Health Service, 1978-1980; Emergency Room Physician, 1980-1981, Miami Inspiration Hospital, Miami, Arizona; Neurology Private Practice, 1984-1988, Las Cruces, New Mexico; Assistant Professor

of Neurology, 1990-1992, Department of Neurology, University of Cincinnati School of Medicine, Cincinnati, Ohio; Assistant Professor of Neurology, 1992-1998 and Associate Professor of Neurology, 1998, Mayo Medical School; Vice Chairman, Department of Neurology, 1994-1998, Mayo Clinic, Scottsdale, Arizona; Assistant Adjunct Professor, 1997-1998, Department of Psychology, University of New Orleans, New Orleans, Louisiana; Associate Attending Neurologist, 1998-2002, Memorial Hospital for Cancer and Allied Diseases, New York, New York; and Associate Member, 1998-2002, Memorial Sloan-Kettering Cancer Center, New York, New York. During this time, I have observed problems with patient compliance with medication regimens, and I have performed research in the area of compliance with medication regimens, including the development of compositions and methods including visual markers used in determining compliance with medication regimens, such as the subject of the '151 Application.

In addition to my research, I belong to the following scientific and medical societies: American Academy of Neurology (Facilitator, Physical Treatments of Chronic Pain, American Academy of Neurology Therapeutics and Technology and Assessment Subcommittee, May, 1992-1996; Member, American Academy of Neurology Continuum Committee on Pain, Kenneth Casey, Facilitator, March, 1994); American Pain Society; Eastern Pain Society; International Association for the Study of Pain; and the Western Pain Society. I have also served on nine Editorial Boards, including the Journal of Clinical Outcomes Management, [2000 (ad hoc reviewer)].

I have reviewed U.S. Patent No. 5,458,879 (Singh). Singh discloses an oral pharmaceutical composition including a water-soluble mucoadhesive. Singh also discloses that colorants may be used as excipients in the composition. Particularly,

Singh describes that these colorants are optional ingredients, which are used to provide a pleasant looking final product. In my opinion, the colorants of Singh are used only to impart an aesthetic quality, namely, color, to the composition. The maximum concentration of colorant in the composition is disclosed in Singh as being 0.03% weight per volume. In my opinion, a colorant concentration of 0.03% weight per volume would not provide a contact coloration of mucous or buccal membranes of the oral/pharyngeal cavity that would be visually observable following ingestion by a patient. Further, in my opinion, a colorant having a concentration of 0.03% weight per volume would not have a half-life comparable to the half-life of the active ingredients in the composition.

I have reviewed U.S. Patent No. 6,200,604 (Pather). Pather is directed to a sublingual buccal effervescent. Pather does list various coloring agents in an oral composition. However, in my opinion, these coloring agents find their use solely for the purpose of imparting a particular color to the composition of Pather. In other words, like the colorants of Singh, the colorants of Pather are used to provide an aesthetic, cosmetic characteristic (color) to the composition. The maximum concentration of colorant in the composition is disclosed in Singh as being 3.5 weight percent of the total composition. In my opinion, the colorants disclosed and the concentrations disclosed in Pather would not have a half-life comparable to the half-life of the active ingredients in the composition disclosed in Pather.

I have reviewed U.S. Patent No. 5, 272,137 (Blase). Blasé discloses an aqueous pharmaceutical suspension including a suspension stabilizing effective amount of xanthan gum and microcrystalline cellulose. Blase also discloses that colorants may be used as excipients in the composition. However, in my opinion, the colorants of

Blasé are used only to impart an aesthetic quality, namely color, to the composition. The maximum concentration of colorant in the composition is disclosed in Blase as being 0.003 g/100 ml of the composition. In my opinion, a colorant concentration of 0.003 g/100 ml would not provide a contact coloration of mucous or buccal membranes of the oral/pharyngeal cavity that would be visually observable following ingestion by a patient. Further, in my opinion, a colorant having a concentration of 0.003 g/100 ml would not have a half-life comparable to the half-life of the active ingredients in the composition as disclosed in Blase.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further Declarant sayeth naught.

March 18, 2005
Date

Gilbert R. Gonzales